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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,191	CIFRA ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-114* is/are pending in the application.

4a) Of the above claim(s) *2-23,30,31,36-67,73,76-98,111 and 112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,24-29,32-35,68-72,74,75,99-110,113 and 114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/09/06&09/05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-114 are presented for examination.

Applicant's Amendment filed August 15, 2006 has been received and entered into the present application. Applicant's Information Disclosure Statements (IDS) filed March 9, 2006 (one page) and September 5, 2006 (three pages) have each been received and entered into the present application. As reflected by the attached, completed copies of form PTO-1449 (four pages total), the Examiner has considered the cited references, except for the Nakamura et al. reference, which was not provided to the Examiner.

Claims 1-114 are pending. Claims 2-23, 30-31, 36-67, 73, 76-98 and 111-112 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 1, 24, 29, 34-35, 68, 72, 99, 100 and 103 are amended and claims 105-114 are newly added. Claims 1, 24-29, 32-35, 68-72, 74-75, 99-110 and 113-114 are under examination.

Applicant's arguments, filed August 15, 2006, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Applicant's Traversal Regarding the Withdrawal of Claims 30-31 and 73

Applicant's disagreement with the withdrawal of claims 30-31 and 73 as noted at page 24 of the remarks has been noted. However, examination of the present claims was performed insofar as the claims read upon the use of the compound zinc citrate as the active agent of the presently claimed method for increasing elastin content in a tissue, pursuant to Applicant's election of January 6, 2006. Claims 30-31 and 73 are properly withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) since they are not directed to the elected species of compound (i.e., zinc citrate) and are drawn to non-elected subject matter, i.e., zinc acetate or zinc chelates.

Claim Rejections - 35 USC § 112, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 24-29, 32-35, 68-72, 74-75, 99-110 and 113-114 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claims 1, 24, 68 and 105 and the claims dependent therefrom are directed to a method for increasing the elastin content in a tissue, such as the lens of the eye, comprising the application of a dermatologically or pharmaceutically acceptable composition consisting essentially of one or more zinc-containing components (such as zinc citrate) in admixture with a dermatologically or pharmaceutically acceptable carrier, in an elastin increasing effective amount, wherein the zinc containing components do not include zinc oxides or zinc pyrithione.

In particular, Applicant has failed to provide adequate written support to now exclude the use of zinc pyrithione as a zinc-containing component of the claimed method.

Regarding Applicant's newly added limitation to exclude zinc oxides or zinc pyrithione from the zinc-containing components to be applied to the tissue(s) in need of increased elastin content, Applicant fails to direct the Examiner to a specific portion of the specification that provides adequate written support to now exclude zinc pyrithione from the claimed zinc-containing components. Applicant's recitation of each of the zinc salts in the alternative provides adequate written support for the exclusion of zinc oxides from the claimed composition.

However, the specification lacks any reference to or recitation of zinc pyrithione as a possible component of the zinc-containing composition of the method. The generic disclosure of zinc salts does not provide adequate written support to now claim a specific species of zinc salt, i.e., in the present case, zinc pyrithione, that was not explicitly taught or suggested for use in the presently claimed method for increasing elastin content in a tissue. This is a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately support, either explicitly or implicitly, by the original disclosure. It is, therefore, clear that Applicant was not in possession of the concept of excluding the compound zinc pyrithione from the zinc composition of the claimed method at the time of the invention.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of excluding the zinc compound zinc pyrithione from use in the claimed method for increasing the elastin content of a tissue.

Accordingly, for these reasons, claims 1, 24-29, 32-35, 68-72, 74-75, 99-110 and 113-114 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-72, 74-75 and 102-104 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention, for the reasons of record set forth at pages 7-9 of the previous Office Action dated February 15, 2006, of which said reasons are herein incorporated by reference.

Applicant states that the Examiner's suggested interpretation of the claims is not the broadest reasonable interpretation consistent with the specification as required by MPEP §2111 and that the rejection disregards the teachings of the specification, namely that the lens of the eye is treated with Applicant's inventive zinc-containing compositions.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

In response to Applicant's argument that the specification defines one possible embodiment wherein the objective of increasing the elastin content of the eye in achieved via the placement of a contact lens comprising one or more zinc-containing components over the lens of the eye, whereby the contact lens releases zinc ions onto the locus of the lens of the eye and/or adjacent tissues, it is noted that the embodiment upon which Applicant relies (i.e., the placement of the contact lens into the lens of the eye) is not what is recited in the rejected claims. Applicant's claim only require that the zinc-containing components be provided in the "vicinity of the lens", but does not provide any disclosure or limiting definition as to the boundaries of what is considered inside the "vicinity of the lens" and what is considered outside the "vicinity of the lens". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please see *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is, therefore, not sufficient for Applicant to claim a method of increasing elastin content of the lens of the eye by providing in the vicinity of the lens one or more zinc-containing components, but fail to set forth clearly, deliberately and precisely the intended area in which the zinc-containing components may be applied and still be considered within "the vicinity of the lens". In the absence of such description, the skilled artisan would not have been reasonably apprised of the scope of the claims. Though a single embodiment of applying the zinc composition directly to the lens may appear in the

specification, it is the claims that must be able to stand alone in defining the invention fully, clearly and precisely. Because the claims only recite the application of the zinc composition "in the vicinity of the lens" with no definitive definition as to the boundaries of the region considered "in the vicinity of the lens" such that the skilled artisan would be able to readily identify what was inside and what was outside the "vicinity of the lens", the claims are indefinite and do not precisely define the invention for which Applicant is seeking protection. Accordingly, the claims continue to fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and remain properly rejected.

For these reasons, and those previously made of record at pages 7-9 of the previous Office Action dated February 15, 2006, rejection of claims 68-72, 74-75 and 102-104 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 24-29, 32-35, 68-72, 74-75, 99-110 and 113-114 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Petrus (U.S. Patent No. 6,573,299; Issued June 2003, Filed September 1999) in view of Riordan (U.S. Patent No. 5,866,142; 1999) and Ogle (U.S. Patent No. 6,113,636; 2000), each already of record, for the reasons of record set forth at pages 9-17 of the previous Office Action dated February 15, 2006, of which said reasons are hereby incorporated by reference.

Newly added claims 105-110 and 113-114 are properly included in the present rejection because Petrus teaches a method for the treatment of orbital disorders associated with the aging eye, including the improvement of age-related changes to the eyelids, such as dry skin or wrinkles (col.2, lines 22-24), by applying a topical composition comprising a penetration enhancer and one or more bio-affecting agents (col.2, lines 24-28), such as zinc citrate (col.13, lines 21-28), wherein the bio-affecting agent penetrates the underlying tissue into the vascular network of the orbit via application to the eyelid surface (col.15, lines 31-32), and further wherein the composition may also comprise emollients (col.14, lines 20-24), provided that the inclusion of such an additive does not defeat the objective of the invention (col.14, lines 34-35).

Riordan provides teachings that the aging process, particularly the lateral folds of the eyes, is characterized by a loss of elastin, thereby producing wrinkles (col.2, lines 18-34). It would have been *prima facie* obvious to one of ordinary skill in the art that the teachings of Petrus regarding the improvement of wrinkles in the peri-orbital region would necessarily involve the increase of elastin content in such a tissue, since wrinkles were known to result from a loss of elastin. In other words, the amelioration of wrinkles as taught by Petrus would necessarily involve increasing the elasticity of the skin via increasing the elastin content of said skin.

Additionally, Petrus expressly teaches variation in the concentration of the active agents depending upon the bioavailability, potency, surface area to which it is applied, composition used and the amount of penetrating agent used (col.6, lines 56-60). Accordingly, the determination of optimum concentration of zinc citrate component of Petrus would have been a matter well within the purview of

one of ordinary skill in the art and would have been made in accordance with such factors described *supra* and further in view of, but not limited to, the age, weight, sec, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, i.e., the activity, efficacy, pharmacokinetics and toxicology profiles of the compound(s) used, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. The concentration(s) of the zinc compound that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific concentration(s) are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentration of zinc is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Lastly, it is further noted that the teaching of "zinc citrate" (i.e., Applicant's elected species of zinc compound) as the zinc component of Petrus meets Applicant's newly added limitation(s) directed to "wherein the zinc-containing components do not include zinc oxides or zinc pyrithione." (see present claim 1, for example)

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

Applicant states that Riordan does not limiting the wrinkling process to the loss of elastin, but rather teaches that the aging process is characterized by both the loss of elasticity and the loss of moisture. Applicant further submits that Riordan fails to mention zinc in any form and that the combination of Riordan and Petrus does not teach the claimed invention, unless one were to use improper hindsight reconstruction. Applicant additionally states that Ogle does not remedy the deficiencies of Petrus or Riordan and that Riordan actually teaches away from the proposed combination because Riordan is

directed to the removal of divalent cations from the skin and, thus, since zinc is a divalent cation, one of skill in the art following the teachings of Riordan would have sought to remove zinc from the skin rather than adding it to the skin.

The fact that Riordan teaches that the wrinkling process is due to both the loss of elasticity and the loss of moisture does not negate the teaching that the formation of wrinkles is due, at least in part, to the loss of elasticity, i.e., loss of elastin, which confers the property of elasticity to the skin, from the skin. Although the loss of moisture may also play a role in the formation of wrinkles, the amelioration of wrinkles as taught by Petrus would necessarily involve improving both the elasticity of the skin and the moisture content of the skin. In other words, the method taught by Petrus for ameliorating peri-orbital wrinkles of the eye skin and dry skin in and around the eye using the composition of zinc citrate would inherently involve the improvement of both the elastin content (i.e., to improve skin elasticity) and the moisture content (i.e., to improve skin dryness) of the peri-orbital skin in order to achieve the therapeutic objective.

Applicant presents arguments against Riordan, stating that the reference does not teach the use of zinc in any form, and also against Ogle for failing to remedy the deficiencies of the combination of Petrus and Riordan because the reference does not disclose or suggest the increase in elastin. However, Applicant is reminded that the rejections made under 35 U.S.C. 103(a) are based upon the combination of references. Applicant clearly does not address the combined teachings as a whole, but rather focuses solely on the discrete teachings of each of the cited references and asserts that, since neither reference teaches the presently claimed invention in its entirety, that the rejection is improper. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references.

Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, rejections under 35 U.S.C. 103(a) are based upon combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one of ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather the test in what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please see also *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Regarding Applicant's argument that the Examiner has used improper hindsight to arrive at the presently claimed invention, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Considering the fact that the present rejection under 35 U.S.C. 103(a) relies solely on the knowledge that was generally available to one of ordinary skill in the art at the time of the invention and does not improperly rely upon Applicant's disclosure, the assertion that the present rejection is made with impermissible hindsight reconstruction is not found persuasive.

Applicant additionally argues against the teachings of Riordan by asserting that the reference teaches away from the proposed combination. Applicant submits that, "Riordan is directed to preventing wrinkles by eliminating divalent cations in the skin by using divalent cation chelators, such as histidine or EDTA. This is significant because zinc, as found in zinc citrate, is also a divalent cation. There is not

teaching in Riordan that some divalent cations (viz. zinc) should be allowed to remain in the skin because they could be beneficial...Thus, based on the complete teachings of Riordan, one of ordinary skill in the art would seek to remove divalent cations (e.g., zinc) from the skin, rather than adding them to the skin. Thus, Riordan teaches away from the proposed combination." (page 31 of Applicant's remarks)

However, Applicant is attempting to bodily incorporate the teachings of Riordan into the teachings of the primary reference without considering the context in which Riordan was cited and the teachings gleaned from the reference and relied upon for the basis of the rejection. Applicant is reminded that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present instance, Riordan was cited for its teaching of the aging process of skin (e.g., loss of elastin in the skin) and also for its teaching that the formation of wrinkles at the lateral folds of the eyes is specifically due to the chronic net loss of elastin in the skin (see Riordan, col.2, lines 18-34). The fact that Riordan may teach another method, different from that of Applicant, by which wrinkles may be treated or prevented, is immaterial to the fact that Riordan expressly supports the conclusion that the methods of Petrus would have necessarily resulted in the increase of elastin content in the tissues in and around the eye area.

For these reasons, and those set forth at pages 9-17 of the previous Office Action dated February 15, 2006, rejection of claims 1, 24-29, 32-35, 68-72, 74-75, 99-110 and 113-114 remains proper and is **maintained**.

Conclusion

Rejection of claims 1, 24-29, 32-35, 68-72, 74-75, 99-110 and 113-114 is proper and is **maintained**.

Claims 2-23, 30-31, 36-67, 73, 76-98 and 111-112 remains **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Leslie A. Royds
Patent Examiner
Art Unit 1614

October 23, 2006

10/24/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER